



(Translation)

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NOTIFICATION OF REASONS FOR REJECTION

Patent Application No.: 511426/94

Examiner's Notice Date: February 20, 2004

Examiner: Eiji Tababori

This application is rejected on the grounds stated below. Any opinion about the rejection must be filed within THREE MONTHS of the mailing date hereof.

REASONS

1. The invention described in Claim 39 of the present application is directed to a diagnosing method for humans and therefore it is unpatentable under the main provision of Section 29(1) of the Patent Law, on the grounds that it does not appear to be industrially available.

2. The invention is unpatentable under Section 29 (1) (iii) of the Patent Law as being described in the following publication distributed in Japan or a foreign country prior to this application.

## Remarks

Claims 23 and 24  
Reference 1  
Notes:

Reference 1 discloses a rat protein of 94 kDa and it is noted that this protein includes an antigenic fragment of a prostate-specific membrane antigen such as of the present application. (See Proc. Natl. Acad. Sci. USA., Vol. 93, No.2 (1996) pages 749 to 753 (Document 1), if necessary.)

Claims 23 and 24  
Reference 2  
Notes:

Reference 2 discloses a human protein of 75 kDa and it is noted that this protein includes an antigenic fragment of a prostate-specific membrane antigen such as of the present application. (See J. Biol. Chem., Vol. 273, No. 32 (1998) pages 20417 to 20424

(Document 2), if necessary.)

Claims 27 to 30 and 32 to 34

Reference 1

Notes:

Reference 1 discloses a polyclonal antibody to be bound to rat protein of 94 kDa and it is noted that the antibody is bound to an antigenic fragment of a prostate-specific membrane antigen such as of the present application. (See Proc. Natl. Acad. Sci. USA., Vol. 93, No.2 (1996) pages 749 to 753 (Document 1), if necessary.)

3. The invention is unpatentable under Section 29 (2) of the Patent Law, as being such that the invention could easily have been made by a person with ordinary skill in the art to which the invention pertains, on the basis of the invention described in the following publication(s) distributed in Japan or a foreign country prior to this application.

Claims 27 to 34

References 1 and 2

Notes:

It would be easily achievable for a person having ordinary skill in the art to obtain an antibody to be bound to a protein disclosed in Reference 1 or 2 by using the protein as an immunogen.

4. The application fails to satisfy the requirements under Section 36 (4) or (5) and (6) of the Patent Law, on the grounds that the specification and the drawing(s) are defective in the following respect(s).

(1) The recitation of Claim 1 is not definite as to the scope of peptide covered by the term "antigenic fragment". Thus, this claim is unclear with regard to the matters essential to the structure of the invention recited in the claim. This also case for the inventions recited in Claims 5, 6, 23 and 26.

(2) The recitation of Claim 2 is not definite as to the element i) "a fragment that is characterized by its antigenicity ..." and the scope of peptide included in the fragments recited in the elements h) to j). Thus, this claim is unclear with regard to the matters essential to the structure of the invention recited in the claim. This also case for the

invention recited in Claim 24.

(3) The recitation of Claim 6 is not clear as to under what condition it "hybridizes specifically to a nucleic acid", and as to the scope of DNA, which is a chemical substance. Thus, this claim is unclear with regard to the matters essential to the structure of the invention recited in the claim.

(4) Claim 6 recites "which hybridizes specifically to a nucleic acid according to any one of Claims 1 to 5"; however, the nucleic acids recited in Claims 1 to 5, contain a sequence that has a degeneration relationship with regard to a natural sequence, and therefore the recitation of this claim is technically not appropriate.

(5) Claim 13 recites an invention of the plasmid deposited under ATCC75294. The Detailed Description of the Invention describes that the plasmid was deposited in the ATCC on August 14, 1992. Nevertheless, a copy of the deposit certificate that certifies the deposit of the plasmid is not attached to the application. Therefore, it is not judged that the invention recited in this claim is described sufficiently in the Detailed Description of the Invention for a person having ordinary skill in the art to be able to easily carry out the invention.

(6) Claims 18 and 19 contains the expression "... which hybridizes specifically to a nucleic acid", which does not specifically describe of what nucleotide sequence the nucleic acid is made. Thus, the scope in which the nucleic acid is covered is not definite. Therefore, the claim is unclear with regard to the matters essential to the structure of the invention recited in the claim.

(7) Claim 32 recites an invention of a composition; however, the composition is not described definitely as to what components in combination it is made of, or the composition ratio is not described or the composition is not specified by its usage or characteristics. Therefore, this claim is unclear with regard to the matters essential to the structure of the invention recited in the claim. This also case for the inventions recited in Claims 33 to 36.

(8) Claim 36 does not indicate its pharmaceutical usage in terms of the pharmacological effect. Further, the end of this claim does not match with that of the claim from which Claim 36 is dependent, and therefore the recitation of this claim is not appropriate. (The pharmacological effect should be described in general pharmacological terms.)

(9) The invention of "use" recited in Claims 38, 39, 41 and 42, is not clear as to what category of patent it belongs to, that is, it is a "product", "method" or "method of producing the product".

The claims not mentioned in this Official Action are not rejected. If a new reason for rejection is noticed, a further Official Action will be issued.

#### LIST OF REFERENCES

1. J. Biol. Chem., Vol. 265, No. 34 (1990) pages 2197 to 21301
2. J. Biol. Chem., Vol. 261, No. 29 (1986) pages 13551 to 13555

If the applicant has any questions or wishes to have an interview, please contact the following Examiner: Eiji Takabori, the 3rd Division of Patent Examination (Biotechnology), Tel. 03-3581-1101, Extension 3447 to 3448